Dianne M. Nast
(N.J. #012611976)
NastLaw LLC
1101 Market Street
Suite 2801
Philadelphia, Pennsylvania 19107
Telephone (215) 923-9300

ATTORNEY FOR PLAINTIFF

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KPH HEALTHCARE SERVICES, INC. A/K/A KINNEY DRUGS, INC., on behalf of itself and all others similarly situated, Plaintiff, v. AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, AMARIN CORPORATION PLC, BASF AMERICAS CORPORATION, BASF CORPORATION, BASF PHARMA (CALLANISH) LTD, BASF USA HOLDING LLC, CHEMPORT, INC., NISSHIN PHARMA, INC., NOVASEP LLC, NOVASEP, INC., GROUPE NOVASEP SAS, AND FINORGA SAS, Defendants.	Case No.: _____ **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff KPH Healthcare Services, Inc. ("Plaintiff" or "KPH") brings this action on behalf of itself and all others similarly situated against Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, Amarin Corporation PLC (collectively "Amarin"); BASF Americas Corporation, BASF Corporation, BASF Pharma (Callanish) Limited, BASF USA Holding LLC (collectively "BASF"); Chemport, Inc. ("Chemport"); Nisshin Pharma, Inc.

("Nisshin"); Novasep, LLC, Novasep, Inc., Groupe Novasep SAS, Finorga SAS (collectively "Novasep," together with Amarin, BASF, Chemport, and Nisshin, "Defendants"). These allegations are based on investigations of counsel, publicly available materials and knowledge, information, and belief.

INTRODUCTION

1. This case arises from Defendants' illegal scheme to delay competition in the United States and its territories for Vascepa, a prescription medication approved by the U.S. Food and Drug Administration ("FDA") to treat hypertriglyceridemia in adults, by hoarding the world's supply of the active pharmaceutical ingredient ("API") needed to make the drug. Plaintiff seeks overcharge damages arising from Defendants' unlawful scheme.

2. Icosapent ethyl ("IPE") is the active ingredient in Vascepa and is made from eicosapentaeonic acid ("EPA"), an omega-3 fatty acid found in fish oil. Vascepa has been shown both to lower triglycerides and to reduce the risk of cardiovascular events in patients who have high triglycerides (150 mg/dL or higher). In 2020, annual sales of Vascepa in the United States were over $600 million.[1]

3. In September and October of 2016, four drug companies filed applications with the FDA seeking approval to launch their generic versions of Vascepa: Roxane Laboratories, Inc. and related entities, later acquired by Hikma Pharmaceuticals Plc ("Hikma"), Dr. Reddy's Laboratories Inc. ("DRL"), Teva Pharmaceuticals USA, Inc. and related entities ("Teva"), and

[1] "Amarin Provides Preliminary 2020 Results and 2021 Outlook" (Jan. 7, 2021), https://investor.amarincorp.com/news-releases/news-release-details/amarin-provides-preliminary-2020-results-and-2021-outlook (last accessed Jun. 1, 2021).

Apotex, Inc. ("Apotex").[2] Hikma, DRL, and Teva each contended that all of the asserted patent claims were either invalid or not infringed by their respective generic version of Vascepa.

4. Amarin sued each of these generics contending that some of the asserted patent claims were either invalid or not infringed by Apotex's generic version of Vascepa, but did not challenge all of the asserted patent claims.

5. In May 2018, Amarin settled with Teva and Amarin settled with Apotex in June 2020. Pursuant to those agreements, Teva and Apotex agreed to forego selling their respective generic versions of Vascepa in the United States until August 9, 2029, or earlier under certain circumstances.

6. Hikma and DRL, however, continued their patent fight and on March 30, 2020, Chief Judge Miranda M. Du of the United States District Court for the District of Nevada, held that Amarin's patents were invalid due to obviousness.

7. After its patent victory, DRL immediately began preparations to launch generic Vascepa, "only to discover that Amarin had foreclosed all the suppliers of the icosapent ethyl API who have sufficient capacity to support a commercial launch in a timely manner."[3]

8. Hikma received FDA approval to launch its generic version of 1mg Vascepa on May 22, 2020.[4]

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[2] Applications were previously filed with the FDA, but they were rejected after Amarin successfully extended its New Chemical Entity exclusivity period, rendering those earlier-filed applications premature.

[3] Complaint, Doc. No. 1, *Dr. Reddy's Laboratories Inc. v. Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation PLC*, No. 3:21-cv-10309-BRM-ZNQ (D.N.J. Apr. 27, 2021) ("DRL Complaint"), ¶ 3.

[4] "Hikma receives FDA approval for its generic Vascepa," PR Newswire (May 22, 2020), https://www.prnewswire.com/news-releases/hikma-receives-fda-approval-for-its-generic-vascepa-301064061.html (last accessed Jun. 1, 2021).

9. On August 7, 2020, DRL received final FDA approval to launch its generic version of 1mg Vascepa.[5] As of that date, DRL had removed all legal and regulatory barriers to its entry into the market for 1mg Vascepa. However, DRL has been unable to enter the market for generic Vascepa due to Amarin's use of a series of exclusive contracts and other anticompetitive conduct to lock up the available supply of IPE, the active pharmaceutical ingredient in Vascepa.

10. On September 3, 2020, Amarin lost its appeal of Judge Du's March 30, 2020 invalidity order.

11. On November 5, 2020, Hikma was able to launch its generic Vascepa product but—hampered by Amarin's anticompetitive cornering of the world's supply of IPE—Hikma launched only limited amounts of its 1mg generic Vascepa.

12. Amarin was able to prevent DRL's generic Vascepa launch and limit Hikma's launch by purposely contracting with at least four different API manufacturers[6]—one or two is standard in the pharmaceutical industry—using agreements that prevent these suppliers from selling IPE API to any other manufacturer,[7] and has otherwise foreclosed access to at least one other major supplier.

13. Amarin has no legitimate procompetitive reason for entering into exclusive supply agreements with these four manufacturers. The total annual capacity of these suppliers has been

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[5] Product Details for ANDA 209499, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=209499#312 (last accessed Jun. 1, 2021).

[6] Nisshin Pharma Inc., Equatez Ltd., Chemport Inc., and Novasep.

[7] *See*, *e.g.*, Amarin Corp. plc, Quarterly Report (Form 10-Q), at 16 (Nov. 8, 2011) ("Following FDA approval of [Vascepa] both agreements [with Equateq and Chemport] include annual purchase levels enabling Amarin to ***maintain supply exclusivity*** with each respective supplier") (emphasis added).

more than triple Amarin's requirements at relevant times in the past, and is at least double Amarin's current requirements.

14. Notably, Amarin has repeatedly bragged about its anticompetitive scheme to investors, often coyly referring to "taking advantage of manufacturing barriers to entry,"[8] but sometimes bluntly stating that the addition of a new supplier "fortifies Amarin's efforts to shield its Vascepa patent beyond its scheduled 2030 expiration."[9]

15. As a result of Amarin's scheme, DRL's launch of generic Vascepa has been delayed since August 2020, Hikma's launch of generic Vascepa has been constrained by limited supply, and Plaintiff and members of the class (defined below) have been forced to pay supracompetitive prices for Vascepa and its generic equivalent.

JURISDICTION AND VENUE

16. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by the Plaintiff and members of the class resulting from Amarin's unlawful monopolization of the United States market for icosapent ethyl, and from the Defendants' conspiracy to restrain trade in the same market.

17. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), § 1337(a), 1407, and 15 U.S.C. § 15.

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[8] Amarin Corp. plc, Annual Report (Form 10-K), at 3 (Feb. 29, 2012).

[9] Press Release, Amarin Corp. plc, "Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa® Active Pharmaceutical Ingredient Supplier" (Apr. 18, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application (last accessed Jun. 1, 2021).

18. Venue is proper in this District under 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because the Defendants transact business within this District and/or have agents in and/or that can be found in this District.

19. The Court has personal jurisdiction over each of the Defendants. Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District. Personal jurisdiction lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary defendants.

THE PARTIES

A. Plaintiff

20. Plaintiff KPH Healthcare Services, Inc., a/k/a. Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of McKesson Corporation, who directly purchased Vascepa from Amarin during the Class Period. As a result of Amarin's alleged anticompetitive conduct, KPH paid supra-competitive prices for its Vascepa purchases and KPH was injured by the illegal conduct alleged herein. Absent the unlawful conduct alleged herein, KPH would have purchased less expensive generic alternatives, rather than branded Vascepa.

B. Defendants

21. Defendant Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principle place of business at 1430 Route 206, Bedminster, NJ 07921.

22. Defendant Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

23. Defendant Amarin Corporation plc is a company incorporated under the laws of England and Wales with principal executive offices at 77 Sir John Rogerson's Quay, Block C, Gran Canal Docklands, Dublin 2, Ireland. Defendants Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc are collectively referred to herein as "Amarin."

24. Defendant BASF Americas Corporation is a company organized and existing under the laws of Delaware with its principle place of business at 1105 North Market Street, Suite 1306, P.O. Box 8985, Wilmington, DE 19899.

25. Defendant BASF Corporation is a company organized and existing under the laws of Delaware with its principle place of business at 100 Park Avenue, Florham Park, NJ 07932.

26. Defendant BASF Pharma (Callanish) Limited is a company incorporated under the laws of England with registered offices at 2 Stockport Exchange, Railway Road, Stockport, SK1 3GG, United Kingdom.

27. Defendant BASF USA Holding LLC is a company organized and existing under the laws of Delaware with its principle place of business at 100 Park Avenue, Florham Park, NJ 07932. Defendants BASF Americas Corporation, BASF Corporation, BASF Pharma (Callanish) Limited, and BASF USA Holding LLC are collectively referred to herein as "BASF."

28. Defendant Chemport Inc. is a company incorporated under the laws of the Republic of Korea with its principal place of business at 15-1, Dongsu-dong, Naju-si, Jeollanam-do 520-330 Korea.

29. Defendant Nisshin Pharma, Inc. is a company incorporated under the laws of Japan with its principal place of business at 25, Kanda-Nishiki-cho 1-chome, Chiyoda-ku, Tokyo 101-8441, Japan.

30. Defendant Novasep, LLC is a company organized and existing under the laws of New Jersey with its principal place of business at 23 Creek Circle, Boothwyn, PA 19061.

31. Defendant Novasep, Inc. is a company organized and existing under the laws of New Jersey with its principal place of business at 23 Creek Circle, Boothwyn, PA 19061.

32. Defendant Groupe Novasep SAS is a company incorporated under the laws of France with its principal place of business at 39, Rue Saint Jean De Dieu Lyon, 69007 France.

33. Defendant Finorga SAS is a company organized and existing under the laws of France with its principal place of business at Route De Givors Chasse Sur Rhone, 38670 France. Defendants Novasep, LLC, Novasep, Inc., Group Novasep SAS, and Finorga SAS are collectively referred to herein as "Novasep."

REGULATORY BACKGROUND

A. Approval of a first entrant

34. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., manufacturers that create a new drug must obtain approval from the FDA to sell the product by filing a New Drug Application ("NDA").[10] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[11]

35. When the FDA approves a brand pharmaceutical manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations*

[10] 21 U.S.C. §§ 301-392.

[11] 21 U.S.C. §§ 355(a), (b).

(the "Orange Book") certain patents that the manufacturer asserts could reasonably be enforced against a manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. After the FDA approves the NDA, the brand manufacturer may list such patents in the Orange Book.[12]

36. When they do not face generic competition, brand manufacturers can usually sell the branded drug far above the marginal cost of production, generating profit margins well in excess of 70% while making hundreds of millions of dollars in sales.

B. Approval of a generic drug

37. The 1984 Hatch-Waxman Amendments to the Food, Drug and Cosmetics Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating their need to conduct extensive human trials or to file lengthy and costly NDAs. Instead of an NDA, a manufacturer seeking approval to sell a generic version of a brand drug may file an Abbreviated New Drug Application ("ANDA"), which relies on the scientific data regarding safety and effectiveness from the brand's original NDA.

38. To gain FDA approval, generic drugs must be bioequivalent to their branded counterparts. Bioequivalence means that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the active ingredient of the brand.[13] Bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and

[12] 21 U.S.C. §§ 355(b)(1), (c)(2).

[13] 21 U.S.C. § 355(j)(8)(B).

may be substituted for one another. The FDA assigns an "AB" rating to generics that meet the necessary criteria in relation to their branded counterparts.

39. An applicant must also certify that its generic version of the drug will not infringe any patents listed in the Orange Book as covering that brand. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications with respect to the branded drug and each listed patent:

a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").[14]

C. The competitive effects of AB-rated generic competition

40. Because generics do not differ therapeutically from brands, the only meaningful basis for competition between them (or between generic versions of the same drug) is price. When there is only one generic competitor on the market, their prices are typically between 10% and 20% lower than their brand counterparts. The discount increases dramatically as more generics enter: when there are multiple generics on the market, the discount off the brand price can be 80% or more. According to the FDA and the FTC, the greatest single drop in generic price occurs when the second generic enters the market.

41. Since passage of the Hatch-Waxman Amendments, every state has adopted "generic substitution" laws that either require or permit pharmacies to substitute an AB-rated

[14] 21 U.S.C. §§ 355(b)(2)(A)(ii)-(iv), (j)(2)(A)(vii)(II)-(IV).

generic when presented with a prescription for its branded counterpart. As a result of these laws and other features of the pharmaceutical marketplace, when generic competition begins (so long as it is un-restrained), brand sales are rapidly converted to generic sales, with generics garnering 80% of unit sales or more within the first six months. The Federal Trade Commission (FTC) has found that, on average, generics capture 90% of brand unit sales within the first year of generic entry and, with multiple generics on the market, prices drop by 85%.

42. Thus, the launch of AB-rated generics typically precipitates significant cost savings for all drug purchasers. It also provides strong incentives for brand manufacturers to forestall such launches.

43. Absent generic competition, brand manufacturers typically sell their drugs at prices far above the marginal cost of production, generating profit margins of 70% and more, sometimes up to 98%. They can do this because, before generic competition, the brand has a monopoly on the drug. When the first generic enters, the brand's monopoly disappears, the generic charges less, and profit margins for the drug begin to shrink. When two or more enter, prices—and profit margins—drop much more precipitously.

44. Brand manufacturers thus have an interest in forestalling generic competition for as long as possible, keeping monopoly profits for themselves. And first filers have an interest in being the only generic on the market for as long as possible, keeping generic sales for themselves.

45. When multiple generic competitors enter the market, the competitive process accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing

costs.[15] Soon after generic competition begins, the vast majority of sales formerly enjoyed by the brand shift to generic sellers. A 2009 FTC Study found that generics captured between approximately 72% and 85% of sales in the first six months.[16] In the end, total payments to the brand manufacturer decline to a small fraction of the amounts paid prior to generic entry. Generic drugs "are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[17]

46. Once the number of generic competitors goes from one to two, there are two generic commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of around 10%. With two generic entrants, the near-term retail price reduction is about 50%. Once third and fourth generics enter, prices drop even lower, until the market is fully "genericized," with price standing as the only meaningful distinction between different products.

47. A noted study of U.S. generic drug prices published in January 2019 found that

> [p]rices typically decrease rapidly with the entry of subsequent generic manufacturers. Generic drugs that entered the market between 2002 and 2014 reduced drug prices by 51% in the first year, and after a plateau in drug prices during the 180-day exclusivity when only the first generic drug manufacturer can market its drug, nearly all reductions in the price of oral medications occurred in the first eight months after generic entry. As the number of generic manufacturers within specific drug markets increases, drug prices continue to decline. A 2005 FDA analysis found that after patent and exclusivity expiration, the

[15] *FTC v. Actavis*, 570 U.S. 136, 144 (2013) (citation omitted).

[16] FTC Study, Federal Trade Commission, "Authorized Generics: An Interim Report," 2009 WL 1785171 (June 2009).

[17] *See* FDA Website, Generic Drugs: Questions and Answers, https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers (last accessed Jun. 1, 2021).

> introduction of one generic manufacturer into the market reduced the price of the drug by only 6%. *With two generic manufacturers, the price reached 52% of the brand-name drug's price*.[18]

48. In general, the more fully genericized the market for a particular drug, the lower the price will be. The presence of multiple generics in the market, competing with the brand and with each other, puts downward pressure on prices, to the benefit of purchasers and consumers.

D. NCE exclusivity

49. A "new chemical entity" ("NCE") is a drug that contains an active moiety—the part of the drug responsible for the physiological or pharmacological action of the drug—that the FDA has not previously approved in another NDA.[19] Approval of an NDA with a new chemical entity provides a five-year exclusivity ("NCE exclusivity") during which the FDA cannot approve an ANDA for a drug containing the same active moiety as the new chemical entity.[20]

E. Supply and use of API in drug products

50. Final drug products and the active pharmaceutical ingredients contained in those products are frequently manufactured by different companies. Where this is the case, the manufacturer of the final drug product, whether brand or generic, combines the API purchased from other sources with inactive ingredients to manufacture the final dosage form. Although a generic manufacturer's process for manufacturing the final dosage form may be different from the manufacturer of the reference listed drug ("RLD"), it is typical for the different

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[18] Gupta, R., et al., Generic Drugs in the United States: Policies to Address Pricing and Competition, *Clin. Pharmacol. Ther.* 2019 Feb; 105(1): 329-337 (emphasis added), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6355356/ (last accessed Jun. 1, 2021); *see also*, Conrad, R. and R. Lutter, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices, FDA Center for Drug Evaluation and Research (2019), https://www.fda.gov/media/133509/download (last accessed Jun. 1, 2021).

[19] 21 C.F.R. § 314.108(a).

[20] 21 C.F.R. § 314.108(b)(2).

manufacturers to use identical API. An RLD is an approved drug product to which a generic version of the drug is compared to show bioequivalence. A generic drug manufacturer must refer to the RLD in its ANDA.

51. As part of the process for obtaining regulatory approval to sell an active pharmaceutical ingredient in the United States, the API manufacturer ordinarily must file a Drug Master File ("DMF") with the FDA. The DMF provides "confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of" the API.[21] The manufacturer of a final dosage form, in turn, references the DMF of each of its API suppliers in its New Drug Application (whether Abbreviated or full).[22] The FDA then reviews the technical information contained in, and inspects the relevant facilities described in, each DMF referenced in the ANDA or NDA. A single DMF may be referenced by multiple manufacturers.

52. If a manufacturer wants or needs to change its API supplier for a drug, it must file a supplement with the FDA referencing the new API supplier's DMF and submit data for drug batches using the new supplier's API. The manufacturer may only market its drug using the new supplier's API if the FDA approves of the change. It is time consuming to prepare and file the necessary supplement and then obtain FDA approval of the change in API supplier.

53. If a current DMF holder is willing, a generic drug manufacturer may use API from an API supplier that already has a DMF on file and reference that DMF in their ANDAs. If, however, no current DMF holder is willing to supply the generic manufacturer with API, it must

[21] Guidelines For Master Drug Files, § I, https://www.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines (last accessed Jun. 1, 2021).

[22] 21 CFR 314.420(b).

identify a new API supplier (who does not yet have a DMF on file) and work with that supplier to develop the API and submit a DMF.

54. It takes significant time to develop a process for manufacturing an API and to then prepare and file the necessary DMF. Generally, because of the significant costs involved in qualifying an API supplier as well as the need to continue to ensure quality control by the API supplier, it is industry practice for both brand and generic drug manufacturers to use only one or two API suppliers to support a drug application.[23]

FACTS

A. Vascepa

55. Vascepa is the brand name for the icosapent ethyl drug produced and marketed by Amarin using the active pharmaceutical ingredient IPE, derived from eicosapentaenoic acid ("EPA"), a type of omega-3 fatty acid derived from fish oil.

56. On July 26, 2012, Amarin received FDA approval to market Vascepa: "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia." Subsequently, the FDA determined that Vascepa was entitled to NCE exclusivity, *see supra* at paragraph 49 for an explanation of NCE exclusivity. Vascepa's NCE exclusivity ran from the NDA approval date to July 26, 2017.

57. On December 13, 2019, the FDA approved a new indication for Vascepa: "as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with

[23] *See*, *e.g.*, Mallu UR, Nair AK, Bapatu HR, Pavan Kumar M, Narla S, et al., "API Supplier Change or Addition of Alternate API Supplier in Generic Drug Products: Cost, Quality and Regulatory Factors" (Pharmaceutical Analytica Acta 2015) at 2 ("[T]wo suppliers shall be selected one as main and another one as alternative supplier for generic DP development.").

elevated triglyceride (TG) levels (≥ 150 mg/dL) and . . . established cardiovascular disease or . . . diabetes mellitus and 2 or more additional risk factors for cardiovascular disease." The new indication is entitled to data exclusivity, which is scheduled to expire on December 13, 2022.

58. Amarin currently markets Vascepa in the 1g and 500mg strengths. Amarin has raised the price of 1g Vascepa dramatically since its launch: the list price for the 1mg strength of Vascepa was estimated to be $308.25 per month in 2019,[24] $355 per month in 2020,[25] and is currently estimated to be around $368.86.[26]

59. Vascepa is Amarin's only product, with revenues of $607 million in 2020.[27]

B. Amarin sets out to corner the world's supply of Vascepa API to prevent generic competition

60. For more than a decade, Amarin has set out to corner the world's supply of IPE, the API for Vascepa, for the explicit purpose of "protecting the potential commercial exclusivity" of its brand Vascepa product.[28]

61. From the outset Amarin has stated its intention to take advantage of manufacturing barriers to entry to prevent competition: "We will seek to protect the potential commercial exclusivity of [Vascepa] through a combination of obtaining and maintaining

[24] "J&J's Xarelto, Amarin's Vascepa are cost-effective, not budget friendly," EndpointsNews (Oct. 18, 2019), https://endpts.com/jjs-xarelto-amarins-vascepa-are-cost-effective-but-not-budget-friendly-icer/ (last accessed Jun. 1, 2021).

[25] "A cardiologist asks: How much is too much to pay for a promising drug?," The Philadelphia Inquirer (Jan. 20, 2020), https://www.inquirer.com/health/expert-opinions/vascepa-price-cardiology-triglycerides-fish-oil-20200122.html (last accessed Jun. 1, 2021).

[26] "Vascepa Prices, Coupons, and Patient Assistant Programs," *https://www.drugs.com/price-guide/vascepa* (last accessed Jun. 1, 2021).

[27] Amarin Corp. plc, Annual Report (Form 10-K), at F-5 (Feb. 25, 2021).

[28] Amarin Corp. plc Annual Report (Form 10-K), at 3 (Feb. 20, 2012).

intellectual property rights and regulatory exclusivity, ***taking advantage of manufacturing barriers to entry*** and maintaining trade secrets."[29]

62. On April 18, 2013, Amarin announced that it had filed a supplemental New Drug Application ("sNDA") to add the API supplier Chemport Inc. ("Chemport").[30] In that announcement Amarin confirmed that the "manufacturing barriers to entry" that it intended to take advantage of are the various exclusive contracts it used to foreclose the supply of Vascepa API: "The addition of Chemport contributes to the planned expansion of the Vascepa manufacturing supply chain and ***is additional progress toward Amarin's goal to protect the commercial potential of Vascepa to beyond 2030 through a combination of patent protection, regulatory exclusivity, trade secrets and by taking advantage of manufacturing barriers to entry***."[31]

63. Amarin's CEO Joseph Zakrewski confirmed that the key barrier to entry was the supply of API, stating that: "The move [to add Chemport as an API supplier] ***also fortifies Amarin's efforts to shield its Vascepa patent beyond its scheduled 2030 expiration***."[32]

64. Amarin explained this anticompetitive strategy in its 2014 Annual Report:

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[29] *Id*. (emphasis added); *see also* Amarin Corp. plc Annual Report (Form 10-K), at 21 (Feb. 27, 2014) ("FDA marketing exclusivity is separate from, and in addition to, patent protection, trade secrets and manufacturing barriers to entry which also help protect Vascepa against generic competition.").

[30] Press Release, Amarin Corp. plc, "Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa® Active Pharmaceutical Ingredient Supplier" (Apr. 18, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application (last accessed Jun. 1, 2021).

[31] *Id*. (emphasis added).

[32] "Amarin wins U.S. nod to add S. Korea supplier," Hartford Business Journal (Apr. 19, 2013) (emphasis added), https://www.hartfordbusiness.com/article/amarin-wins-us-nod-to-add-s-korea-supplier (last accessed Jun. 1, 2021).

> Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors . . . While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive.[33]

65. Amarin expected its scheme to work, and wanted the market to know that fact:

> In April 2012, the FDA published draft guidance for companies that may seek to develop generic versions of Vascepa. If an application for a generic version of Vascepa were filed and if new chemical entity, or NCE exclusivity is not granted to Vascepa, the FDA may accept the filing for review and we would likely engage in costly litigation with the applicant to protect our patent rights. If the generic filer is ultimately successful in patent litigation against us, meets the requirements for a generic version of Vascepa to the satisfaction of the FDA (after any applicable regulatory exclusivity period and, typically, the litigation-related 30-month stay period expires), ***and is able to supply the product in significant commercial quantities***, the generic company could, with the market introduction of a generic version of Vascepa, limit our U.S. sales, which would have an adverse impact on our business and results of operations.[34]

66. Amarin also warned the market that the failure of its anticompetitive scheme was a material investment risk: "Risks Related to our Reliance on Third Parties – We may not be able to maintain our exclusivity with our third-party Vascepa suppliers if we do not meet minimum purchase obligations due to lower than anticipated sales of Vascepa."[35]

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[33] Amarin Corp. plc, Annual Report (Form 10-K), at 40 (March 3, 2015).

[34] Amarin Corp. plc, Quarterly Report (Form 10-Q), at 31 (Aug. 8, 2013) (emphasis added).

[35] Amarin Corp. plc, Quarterly Report (Form 10-Q), at 46 (Nov. 7, 2013); *see also* Amarin Corp. plc, Quarterly Report (Form 10-Q), at 59 (Aug. 7, 2014) ("Certain of our

C. Amarin has, in fact, locked up the world's supply of Vascepa API

67. To effectuate its anticompetitive scheme, Amarin has entered into exclusive or *de facto* exclusive agreements with at least four of the largest suppliers for icosapent ethyl API, and has secured exclusive supply from yet another supplier.

68. In February 2009 Amarin entered into a supply agreement with Japan-based Nisshin Pharma Inc. ("Nisshin") pursuant to which Nisshin agreed to supply Amarin with IPE (referred to as E-EPA in the agreement).[36] Amarin paid Nisshin $500,000 up-front when the agreement was signed, and agreed to pay Nisshin another $500,000 when Amarin obtained approval to market Vascepa either in the U.S. or the European Union.[37] The agreement contained a minimum purchase commitment.[38]

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agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. Similarly, if we terminate certain of our supply agreements, such suppliers may be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive.").

[36] Supply Agreement Between (1) Nisshin Pharma Inc. ("Nisshin") and (2) Amarin Pharmaceuticals (Ireland) Ltd. ("Amarin"), dated February 23, 2009, https://www.sec.gov/Archives/edgar/data/897448/000095016209000453/ex4_86.htm (last accessed Jun. 1, 2021).

[37] *Id*. at 15.

[38] *Id*.

69. Despite the fact that Amarin believed Nisshin was capable of producing sufficient quantities of API to support Amarin's launch of Vascepa,[39] Amarin continued its scheme to amass API supply and suppliers.

70. In June 2011, the BBC reported that Amarin had entered into a supply agreement with Scotland-based Equateq Ltd. ("Equateq") whereby Equateq agreed to supply Amarin with the API needed to manufacture Vascepa.[40] Amarin again committed to significant, long-term purchases: "Under the terms of the contract, Amarin Corporation is committed to buying £6.1m worth of API concentrate from Equateq in year one, rising to £12.3m in year four."[41] In fact, although the CEO of Equateq refused to provide further specifics of the supply agreement, he claimed it was worth £100m over its life.[42]

71. Amarin revealed to investors in August 2011 that the minimum purchase commitment was intended to prevent Equateq from selling Vascepa API to any potential

[39] Amarin Corp. plc, Annual Report (Form 10-K), at 10-11 (February 29, 2012); *see also* Press Release, Amarin Corp. plc, "Amarin Announces Additional Vascepa® (icosapent ethyl) Supplier" (Dec. 11, 2012) ("Amarin's current plan is to launch Vascepa based on product produced by its existing API supplier, Nisshin Pharma"), https://www.globenewswire.com/en/news-release/2012/12/11/510754/18362/en/Amarin-Announces-Additional-Vascepa-R-icosapent-ethyl-Supplier.html (last accessed Jun. 1, 2021).

[40] "Drug firm Equateq secures big US order," BBC News (July 4, 2011), https://www.bbc.com/news/uk-scotland-scotland-business-14013747 (last accessed Jun. 1, 2021).

[41] *Id*.

[42] "Equateq nets £100m deal to supply fish oil for heart treatment," The Scotsman (June 29, 2011), https://www.scotsman.com/business/equateq-nets-ps100m-deal-supply-fish-oil-heart-treatment-1670500 (last accessed Jun. 1, 2021).

competitor of Amarin.[43] Amarin also paid Equateq a $1m "commitment fee" in May 2011.[44] Equateq was acquired by BASF in May 2012.[45]

72. Also in 2011, Amarin secured an exclusive supply contract with Korea-based Chemport Inc. ("Chemport").[46] This agreement also contains minimum purchase requirements to prevent Chemport from selling API to potential generic manufacturers,[47] and Amarin is required to pay Chemport in cash for any shortfall in the minimum purchase obligations.[48] As part of the agreement, Amarin agreed to pay Chemport $1.1 million for the purchase of raw materials and to provide an additional $3.3 million to Chemport as equity investment.[49] During the nine months ended September 30, 2013, the Company made payments of $4.8 million to Chemport.[50]

73. Equateq and Chemport were approved by the FDA to manufacture Vascepa API in April 2013.[51]

74. In December 2012, Amarin announced that it had entered into yet another exclusive agreement with a fourth supplier, an "exclusive consortium" of companies including

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[43] Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011) ("Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport Inc. (see para. 53 below)] include annual purchase levels ***to enable Amarin to maintain exclusivity with each respective supplier***, and to prevent potential termination of the agreements.").

[44] *Id*.

[45] "BASF completes omega-3 portfolio with Equateq buy," NUTRAingredients.com (May 8, 2012), https://www.nutraingredients.com/Article/2012/05/09/BASF-completes-omega-3-portfolio-with-Equateq-buy# (last accessed Jun. 1, 2021).

[46] Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011).

[47] *Id*. ("Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport] include annual purchase levels ***to enable Amarin to maintain exclusivity with each respective supplier***, and to prevent potential termination of the agreements.").

[48] Amarin Corp. plc Annual Report (Form 10-K), at F-25 (Feb. 27, 2014).

[49] *Id*.

[50] Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Nov. 7, 2013).

[51] Amarin Corp. plc Quarterly Report (Form 10-Q), at 13 (May 9, 2013).

Canada-based Slanmhor Pharmaceutical, Inc., Ocean Nutrition Canada, and Novasep (collectively referred to in this Complaint as "the Consortium").[52]

75. As part of the agreement, Amarin agreed to pay up to $2.3 million in development fees and a "commitment" of up to $15 million, credited against future API material purchase.[53] Amarin made payments of $3.9 million to Novasep in the quarter in which the agreement was signed,[54] and an additional $1.4 million in the following quarter.[55] The Novasep agreement includes minimum purchase obligations, and Amarin is required to make cash payments to Novasep in the event of a shortfall.[56] During the nine months ended September 30, 2013, the Amarin made payments of $6.1 million to Novasep.[57]

76. In July 2014 Amarin cancelled the agreement with the Consortium and in July 2015 it entered a new agreement with Novasep directly.[58]

77. Amarin purchased approximately $25.7 million worth of Vascepa API in 2013 from Nisshin and Chemport, and also paid $13.9 million to Novasep related to "commitments," stability and technical batches, and advances on future API purchases.[59]

78. In October 2013, received bad news from the FDA. FDA had voted against broadening Vascepa's indication and had cancelled the special protocol assessment (SPA) status

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[52] Press Release, Amarin Corp. plc, "Amarin Announces Additional Vascepa® (icosapent ethyl) Supplier" (Dec. 11, 2012).

[53] Amarin Corp. plc Quarterly Report (Form 10-Q), at 13 (May 9, 2013).

[54] *Id*.

[55] Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Aug. 8, 2013).

[56] *Id*.

[57] Amarin Corp. plc Quarterly Report (Form 10-Q), at 15 (Nov. 7, 2013).

[58] Amarin Corp. plc Annual Report (Form 10-K), at 14 (Feb. 25, 2016).

[59] Amarin Corp. plc Quarterly Report (Form 10-Q), at 33 (Nov. 7, 2013).

of a clinical trial that Amarin had planned to use the results of to expand the indication of Vascepa. This "was seen by most observers as the death blow for Amarin's efforts to gain wider approval."[60] Although this was expected to result in less-than-hoped-for demand for Vascepa, Novasep and BASF planned to continue supplying Vascepa API at the agreed-upon pace.[61]

79. Finally, Amarin has secured significant additional supply from another Japan-based supplier, Nippon Suisan and, as a result, that company's supply is not available to any U.S. generic.[62]

80. The foregoing agreements between Amarin and the Vascepa API suppliers were intended to and have had the effect of limiting competition in the market for generic Vascepa. As a practical matter, the API suppliers took millions of dollars in payments from Amarin in exchange for an agreement ***not*** to sell the essential API to anyone else, regardless of whether Amarin needed the API for its own production needs or whether there were other market opportunities for the sale of the API.

81. By foreclosing the available API supply from generic competitors, Amarin has been able to capture supracompetitive profits from the inflated sales of Vascepa, and has shared those supracompetitive profits with the API suppliers to buy their complicity in the anticompetitive scheme.

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[60] "Novasep to keep supplying Amarin with Vascepa API," Outsourcing-Pharma.com (Oct. 30, 2012), https://www.outsourcing-pharma.com/Article/2013/10/30/Novasep-to-keep-supplying-Amarin-with-Vascepa-API (last accessed Jun. 1, 2021).

[61] *Id*.

[62] "Amarin: What The Street Hasn't Factored In And Why Amarin Is Worth $80," Seeking Alpha (Oct. 9, 2018) ("Nippon Suisan (1332 JT), or better known as "Nissui" in the Japanese stock market, has 420 tons worth of annual high-grade EPA supply, solely aimed for the further roll-out of Amarin's Vascepa."), https://seekingalpha.com/article/4210747-amarin-what-street-hasn't-factored-in-and-why-amarin-is-worth-80 (last accessed Jun. 1, 2021).

D. Amarin secured a supply of Vascepa API more than double its needs for legitimate business purposes

82. In February 2019, Amarin's CEO John Thero stated that Amarin's anticipated 2019 sales of Vascepa amounted to $350 million, but the company was purchasing API to support sales of more than $700 million.[63] Thero was clear that Amarin was ***not*** raising its guidance or expecting to sell more than $700 million in Vascepa that year, but was merely purchasing excess supply.[64]

83. At the same time that Amarin was purchasing more than twice its supply needs for 2019 from its existing suppliers, Amarin was in the process of locking up an additional 420 tons worth of annual supply.[65] For comparison, the entire U.S. market for Vascepa is estimated to require only 450 tons per year.

E. Amarin's excess supply is economically irrational absent its anticompetitive purpose and contrary to industry practice

84. In Amarin's own words: "The agreements with each of our API suppliers contemplate phased manufacturing capacity expansions designed to create sufficient manufacturing capacity to meet anticipated demand for API material for [Vascepa] following

[63] Amarin Corp. plc Earnings Call (Feb. 27, 2019), https://www.fool.com/earnings/call-transcripts/2019/02/27/amarin-corporation-plc-amrn-q4-2018-earnings-confe.aspx (last accessed Jun. 1, 2021).

[64] *Id*. ("Hey, we could be wrong on our guidance. Our guidance doesn't assume any earlier approval from the FDA. And they had their mind to our product as four-year dating. Dating, one of the things we spent a lot of time in the development of this product was the stability of it and preventing oxidation, etc. So, it's got a long shelf life. So, they figure that that's the right investment to be made.").

[65] "Amarin: What The Street Hasn't Factored In And Why Amarin Is Worth $80," Seeking Alpha (Oct. 9, 2018), https://seekingalpha.com/article/4210747-amarin-what-street-hasnt-factored-in-and-why-amarin-is-worth-80 ("Nippon Suisan (1332 JT), or better known as "Nissui" in the Japanese stock market, has 420 tons worth of annual high-grade EPA supply, solely aimed for the further roll-out of Amarin's Vascepa.") (last accessed Jun. 1, 2021).

FDA approval. Accordingly, Nisshin and our other potential suppliers are currently working to expand and qualify their production capabilities to meet regulatory requirements to manufacture the API for [Vascepa]. These API suppliers are self-funding these expansion and qualification plans ***with contributions from Amarin***."[66]

85. Amarin provided further detail about the expenses necessary to develop and maintain so many API suppliers:

> Among the conditions for FDA approval of a pharmaceutical product is the requirement that the manufacturer's quality control and manufacturing procedures conform to current Good Manufacturing Practice, or cGMP, which must be followed at all times. The FDA typically inspects manufacturing facilities before regulatory approval of a product candidate, such as [Vascepa], and on an ongoing basis. In complying with cGMP regulations, pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting, and other requirements. Our NDA filed with the FDA for [Vascepa] references one supplier of our API, Nisshin, with which we have had the longest relationship and which we believe is qualified to support our initial commercial launch of [Vascepa]. We have defined with the FDA our plan and specifications for qualifying the additional API suppliers. We intend to submit sNDAs[67] for the use of these additional API suppliers after the suppliers successfully complete the specified process and facility qualifications and after the NDA for the MARINE indication is approved.[68]

86. As these public statements confirm, it is expensive and time consuming for each new API supplier to develop, obtain regulatory approval for, and maintain quality control of its API manufacturing process, and Amarin has taken on a significant share of that burden.

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[66] Amarin Corp. plc Annual Report (Form 10-K), at 11 (Feb. 20, 2012) (emphasis added).

[67] Defined in paragraph 62 above.

[68] *Id.*; *see also* Amarin Corp. plc Quarterly Report, at 16 (Nov. 8, 2011) ("We anticipate incurring certain costs associated with the qualification of product produced by [Nishhin, Equateq, and Chemport].").

87. Generally, it is not only possible[69] but less expensive to scale up the supply from an existing manufacturer than it is to qualify additional suppliers. Consequently, standard industry practice is to have only one or two API suppliers. In addition to saving initial setup costs, the benefits of scale result in volume discounts,[70] which Amarin foregoes by engaging additional suppliers with minimum purchase requirements.

88. Given these inefficiencies, the only economic advantages from having four API suppliers, and obtaining excess API inventory, results from the inability of generic competitors to obtain API supply.

F. Amarin's scheme succeeded in thwarting generic competition

89. DRL obtained final FDA approval on August 7, 2020,[71] but has still been unable to secure a supply of API sufficient to support a launch of its generic Vascepa.[72]

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[69] Amarin Corp. plc Annual Report (Form 10-K), at 75 (Feb. 27, 2019) ("our current supply chain is scalable"); *see also*, Amarin Corp. plc Earnings Conference Call Transcript (Feb. 27, 2019) ("We have a supplier network that consists of over 20 independent companies. The API piece of that – we have multiple suppliers on. They're competing with one another. ***And they're interested in expanding capacity***."), *https://www.fool.com/earnings/call-transcripts/2019/02/27/amarin-corporation-plc-amrn-q4-2018-earnings-confe.aspx* (last accessed Jun. 1, 2021).

[70] Amarin Corp. plc Annual Report (Form 10-K), at 75 (Feb. 27, 2019) ("Certain of our API supply agreements contain provisions under which the cost of supply to us decreases as we purchase increased product volume.").

[71] Product Details for ANDA 209400, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=209499#312 (last accessed Jun. 1, 2021).

[72] DRL Complaint at ¶ 81 ("Nonetheless, despite DRL's best efforts to launch in a timely manner, it is still unable to do so. The only reason why DRL still cannot launch is because Amarin contracted with suppliers of icosapent ethyl API not to sell to generic manufacturers including DRL, either through literal exclusive contract or through buying up all available supplies, such that DRL cannot acquire the necessary API to support a timely commercial launch.") *see also id*. at ¶ 8 ("But for Amarin's locking up of the icosapent ethyl API supply, DRL would have been ready, willing, and able to launch in August 2020, upon receiving regulatory approval.").

90. Hikma, on the other hand, was able to launch on November 5, 2020,[73] but was forced to do so in only limited quantities due to supply constraints.[74]

91. For its part, Amarin believes its scheme is working, and—again—wants the market to know this: "We have heard from various suppliers that they have been approached regarding supplying API for generic use. These suppliers informed us that they turned down such approaches for various reasons including that they don't have excess capacity."[75] And in a press release discussing the Court of Appeals decision Amarin knowingly conveyed that generic manufacturers "are likely to have limited supply capacity."[76]

CAUSATION

92. But for the anticompetitive conduct alleged above, generic icosapent ethyl would have entered the market as early as August 2020, the date of DRL's final ANDA approval, because, absent Amarin's anticompetitive conduct, there would have been a sufficient supply of Vascepa API for DRL to do so.

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[73] Press Release, Hikma Pharmaceuticals plc, "Hikma launches Icosapent Ethyl Capsules" (Nov. 5, 2020), https://www.hikma.com/newsroom/article-i4928-hikma-launches-icosapent-ethyl-capsules/ (last accessed Jun. 1, 2021).

[74] "Amarin launches Vascepa in all-important Europe as it slowly bleeds share to U.S. generic," Fierce Pharma (Apr. 6, 2021), https://www.fiercepharma.com/marketing/amarin-launches-vascepa-all-important-europe-as-blockbuster-to-be-heart-drug-slowly (last accessed May 6, 2021).

[75] Amarin Corp. plc Earnings Call Transcript (Apr. 13, 2020), https://www.fool.com/earnings/call-transcripts/2020/04/13/amarin-corporation-plc-amrn-q1-2020-earnings-call.aspx (last accessed Jun. 1, 2021).

[76] Press Release, Amarin Corp. plc, "Amarin Provides Update Following Ruling in Vascepa® ANDA Patent Litigation" (Sep. 3, 2020), https://www.globenewswire.com/news-release/2020/09/03/2088633/0/en/Amarin-Provides-Update-Following-Ruling-in-VASCEPA-ANDA-Patent-Litigation.html (last accessed Jun. 1, 2021).

93. Likewise, absent the Defendants' anticompetitive conduct, Hikma would have launched its generic Vascepa at full supply because, absent Amarin's anticompetitive conduct, there would have been sufficient supply of Vascepa API for Hikma to do so.

94. Instead, Defendants willfully and unlawfully maintained Amarin's monopoly power in the relevant market by engaging in a conspiracy to exclude competition and maintain supracompetitive prices for Vascepa. Defendants implemented their conspiracy *via* their exclusive contracts and other conduct alleged herein.

95. The only impediment to DRL's generic icosapent ethyl entering the market is Defendants' unlawful conduct.

96. Likewise, the only impediment to Hikma's fully supplying demand for generic icosapent ethyl is Defendants' unlawful conduct.

97. Defendants' conspiracy had the purpose and effect of preventing competition to Vascepa, permitting Amarin to maintain supracompetitive prices for Vascepa, enabling Amarin to sell Vascepa without competition, and allowing Amarin to reap monopoly profits (and share those monopoly profits with the API-supplier defendants), to the detriment of purchasers.

CLASS ACTION ALLEGATIONS

98. Plaintiff brings this action as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on its own behalf and as a representative of a class defined as follows:

> All persons or entities in the United States and its territories who purchased Vascepa directly from any of the defendants at any time during the period from August 7, 2020 through and until the anticompetitive effects of Defendants' challenged conduct cease (the "Class Period").

99. Excluded from the Class are the Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

100. Plaintiff's claims are typical of the claims of members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, and all paid artificially inflated prices for Vascepa and were deprived of the benefits of competition from less expensive generic versions as a result of Defendants' conduct.

101. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, the Class.

102. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

103. Questions of law and fact common to the Class include:

a. whether Amarin unlawfully maintained monopoly power through all or part of its overarching scheme;

b. whether Defendants' anticompetitive scheme suppressed generic competition to Vascepa;

c. as to those parts of Defendants' challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which Vascepa is sold;

d. whether direct proof of Amarin's monopoly power is available, and if available, whether it is sufficient to prove Amarin's monopoly power without the need to also define a relevant market;

e. to the extent a relevant market or markets must be defined, what that definition is, or those definitions are;

f. determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic, unfair, and unjust conduct caused;

g. whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

h. whether Defendants' scheme, in whole or in part, has substantially affected intrastate commerce;

i. whether Defendants foreclosed the supply of icosapent ethyl API.

j. whether Amarin possessed the ability to control prices and/or exclude competition for Vascepa during the Class Period;

k. Whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Vascepa;

l. Whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in limiting the amount of generic Vascepa available upon the launch of the first generic icosapent ethyl product;

m. whether Defendants' scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and members of the Class in the nature of overcharges; and

n. the quantum of overcharges paid by Plaintiff and the Class in the aggregate.

104. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently,

and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

105. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

MARKET POWER AND DEFINITION

106. Pharmaceutical products comprising icosapent ethyl have pharmacological properties which differentiate them from other drugs for treating secondary hypertriglyceridemia and enable sellers of such products to earn supra-competitive profits on their sale.

107. At all relevant times, Amarin has had market power over oral capsules (in 1g and 500mg strengths) comprised of icosapent ethyl, *i.e.*, Vascepa and its AB-rated generic bioequivalents, because Amarin has had the power to maintain the price of these products at supra-competitive levels without losing substantial sales to other hypertriglyceridemia products. This market power may be shown directly, and therefore no relevant market needs to be defined.

108. Throughout the relevant time period, Amarin had monopoly power in the market for Vascepa because they had the power to exclude competition and/or raise or maintain the price of Vascepa and generic equivalents at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

109. A small but significant non-transitory increase to the price of brand Vascepa would not have caused a significant loss of sales sufficient to make the price increase unprofitable.

110. Brand Vascepa does not exhibit significant, positive cross-elasticity of demand with respect to price with any other product for the treatment of hypertriglyceridemia.

111. Brand Vascepa is differentiated from all other products currently on the market for treatment of hypertriglyceridemia.

112. Amarin needed to control only brand Vascepa and its AB-rated generic equivalents, and no other products, in order to maintain the price of icosapent ethyl profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions of Vascepa unconstrained by supply issues would render Amarin unable to profitably maintain their prices for Vascepa without losing substantial sales.

113. Amarin had, and exercised, the power to exclude generic competition to brand Vascepa.

114. At all material times, high barriers to entry protected branded Vascepa from the forces of price competition.

115. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Amarin's ability to control the price of Vascepa and generic Vascepa, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (a) generic Vascepa would have entered the market at a substantial discount to brand Vascepa but for Defendants' anticompetitive conduct; (b) Amarin's gross margin on Vascepa at all relevant times was very high; and (c) Amarin never lowered the price of Vascepa to the competitive level in response to the pricing of other brand or generic drugs, and indeed enjoyed rising sales as it dramatically increased the price of Vascepa.

116. To the extent proof of monopoly power by defining a relevant product market is

required, Plaintiff alleges that the relevant antitrust market is the market for Vascepa and its AB-rated generic equivalents.

117. The United States and its territories constitute the relevant geographic market.

118. Amarin market share in the relevant market was 100% prior to Hikma's constrained generic launch, implying substantial monopoly power.

MARKET EFFECTS

119. Amarin willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. Amarin designed a scheme to delay competition on the products' merits to further Amarin's anticompetitive purpose of forestalling generic competition against Vascepa. Amarin carried out the scheme with the anticompetitive intent and effect of maintaining supra-competitive prices for icosapent ethyl.

120. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Vascepa from competition. These actions allowed Amarin to maintain a monopoly and exclude competition in the market for Vascepa and its AB-rated generic equivalents, to the detriment of Plaintiff and all other members of the Class.

121. Defendants' exclusionary conduct delayed generic competition and unlawfully enabled Amarin to sell Vascepa without generic competition. Were it not for Defendants' illegal conduct, one or more generic versions of Vascepa would have entered the market sooner.

122. Defendants' exclusionary conduct also limited Hikma's launch of generic Vascepa, enabling Amarin to sell Vascepa with reduced generic competition.

123. Competition among drug manufacturers enables all purchasers of the drug to buy drugs, including both the original drug and its subsequent competitors, at substantially lower

prices. Consequently, drug manufacturers—and those that share in their profits—have a strong incentive to delay and limit competition, and purchasers experience substantial cost inflation from any such delay or limitation.

124. Defendants' anticompetitive conduct caused Plaintiff and all members of the Class to pay more than they would have paid for Vascepa and generic equivalents absent their illegal conduct.

125. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, Plaintiff and members of the Class would have paid less for icosapent ethyl by (a) paying lower prices on their remaining brand purchases of Vascepa, and/or (b) substituting purchases of less-expensive generic Vascepa for their purchases of more-expensive brand Vascepa.

126. Thus, Defendants' unlawful conduct deprived Plaintiff and members of the Class of the benefits from the competition that the antitrust laws are designed to ensure.

ANTITRUST IMPACT

127. During the relevant time period, Plaintiff and members of the Class purchased substantial amounts of Vascepa indirectly from Amarin. As a result of Defendants' illegal conduct, Plaintiff and the members of the Class were compelled to pay, and did pay, artificially inflated prices for Vascepa. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Vascepa was artificially inflated by Defendants' illegal conduct, and (2) members of the Class have been deprived of the opportunity to purchase lower-priced generic versions of Vascepa. The supracompetitive prices were paid at the point of sale, which is where Plaintiff and the Class suffered antitrust impact.

128. As a consequence, Plaintiff and members of the Class have sustained substantial damages to their business and property in the form of overcharges. The full amount and form of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to Plaintiff and the members of the Class.

129. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top."

130. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution result in higher prices paid by members of the Class.

131. Defendants' anticompetitive actions enabled them to indirectly charge Plaintiff and the Class prices in excess of what they otherwise would have been able to charge absent their unlawful agreements described herein.

132. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

133. The inflated prices the Class paid are traceable to, and the foreseeable result of, the overcharges by Amarin.

EFFECT ON INTERSTATE COMMERCE

134. At all material times, substantial amounts of Vascepa manufactured and sold by

Amarin, were shipped across state lines, and sold to customers located outside their state of manufacture.

135. During the relevant time period, in connection with the purchase and sale of Vascepa, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

136. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged herein, within the flow of, and substantially affecting, interstate commerce.

FIRST CLAIM FOR RELIEF
Violation of Section 1 of the Sherman Act: Contract, Combination, and Conspiracy in Restraint of Trade
(Against All Defendants)

137. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

138. Defendants violated 15 U.S.C. § 1 by entering into a series of exclusive contracts that were intended to and did lock up the supply of Vascepa API, thereby constraining competition in the market for branded and generic Vascepa.

139. The agreements between Amarin and each of the API-supplier defendants substantially, unreasonable, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

a. prevent generic competitors from obtaining the API necessary to manufacture Vascepa;

b. delay the entry of generic versions of Vascepa;

c. hamper the ability of generic competitors to meet demand for their generic Vascepa product; and

d. raise and maintain the prices that Plaintiff and Class members would pay for Vascepa to and at supra-competitive levels.

140. There is no legitimate, non-pretextual, procompetitive business justification for the exclusive contracts between Amarin and the API-supplier defendants.

141. The agreements between Amarin and each of the API-supplier defendants harmed competition in the relevant market.

142. As a direct and proximate result of Defendants' violation of Sherman Act § 1, Plaintiff and the Class have been injured in their business and property throughout the Class Period.

SECOND CLAIM FOR RELIEF
Violation of Section 2 of the Sherman Act: Monopolization
(Against Amarin)

143. Plaintiff incorporates by reference all of the allegations above as though fully set forth herein.

144. As described above, throughout the relevant time period Amarin possessed monopoly power nationwide and in each of the United States and its territories in the market for Vascepa. No other manufacturer sold a competing version of Vascepa during the relevant time period.

145. At all relevant times, Amarin possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Amarin possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

146. Through their overarching anticompetitive scheme, as alleged above, Amarin willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiff and the Class. Amarin's anticompetitive conduct was done with the specific intent to maintain their monopoly in the market for Vascepa in the United States and its territories.

147. Amarin knowingly and intentionally engaged in this anticompetitive scheme to monopolize the market for Vascepa and its generic equivalents as described above. Amarin accomplished this scheme by, *inter alia*, (1) entering into exclusive supply agreements with at least four different icosapent ethyl API suppliers; (2) otherwise foreclosing the supply of icosapent ethyl API; and (3) raising and maintaining prices so that Plaintiff and Class members would pay for Vascepa at supracompetitive prices.

148. The goal, purpose, and effect of Amarin's scheme was to prevent, delay, and limit the sale of generic Vascepa in the United States at prices significantly below Amarin's prices for Vascepa, thereby effectively preventing the average market price of Vascepa and its generic equivalents from declining dramatically while maintaining and extending its monopoly power with respect to Vascepa.

149. Plaintiff and members of the Class purchased substantial amounts of Vascepa directly from Amarin.

150. As a result of Amarin's illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, more than they would have paid for their requirements of Vascepa and its generic equivalents absent Amarin's illegal conduct. But for Amarin's illegal

conduct, competitors would have begun selling generic Vascepa during the relevant period, and prices for Vascepa and its generic equivalents would have been lower, sooner.

151. Had manufacturers of generic Vascepa entered the market and lawfully competed with Amarin earlier, Plaintiff and other members of the Class would have substituted lower-priced generic Vascepa for the higher-priced brand-name Vascepa for some or all of their requirements of Vascepa and its generic equivalents, and/or would have paid lower net prices on their remaining Vascepa and/or AB-rated bioequivalent purchases.

152. Plaintiff and members of the Class will continue to suffer injury, in the form of overcharges paid for Vascepa, if Amarin's unlawful conduct is not enjoined.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on their own behalf and on behalf of the proposed Class, prays for judgment against Defendants and that this Court:

1. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and appoint Plaintiff as the named representative of the Class;
2. Enter joint and several judgments against the defendants and in favor of Plaintiff and the class on all counts;
3. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;
4. Award Plaintiff and the class their costs of suit, including reasonable attorneys' fees as provided by law; and
5. Award such other and further relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demand a trial by jury of all issues so triable.

Dated: June 18, 2021

Respectfully submitted,

/s/ Dianne M. Nast
Dianne M. Nast
Daniel N. Gallucci
Michele S. Burkholder
NASTLAW LLC
1101 Market Street, Suite 2801
Philadelphia, PA 19107
(215) 923-9300
dnast@nastlaw.comdgallucci@nastlaw.com
mburkholder@nastlaw.com

/s/ Michael L. Roberts
Michael L. Roberts
Karen S. Halbert
Stephanie E. Smith
ROBERTS LAW FIRM US, PC
20 Rahling Cir.
Little Rock, AR 72223
(501) 821-5575
mikeroberts@robertslawfirm.us
karenhalbert@robertslawfirm.us
stephaniesmith@robertslawfirm.us

/s/ Linda P. Nussbaum
Linda P. Nussbaum
Peter Moran
NUSSBAUM LAW GROUP, P.C.
1211 Avenue of the Americas, 40th Fl.
New York, NY 10036
(917) 438-9189
lnussbaum@nussbaumpc.com
pmoran@nussbaumpc.com

Counsel for KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. and the Proposed Direct Purchaser Class